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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,024	02/26/2002	Douglas Alan Miller	45568-00040	4446

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EXAMINER	
JACOBSON, TONY M	
ART UNIT	**PAPER NUMBER**
2644	9

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,024	MILLER ET AL.	
	Examiner	Art Unit	
	Tony M Jacobson	2644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,16-28 and 31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,16-28 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 8, 9, 16-23, 26-28, 31, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer (US 6,554,762) in view of Hochmair et al. (US 4,577,641).

3. Regarding claims 1, 16, and 21, Leysieffer discloses in Fig. 1, an implantable hearing aid (12) with means for measuring its coupling quality (a system for assessing the performance of a hearing aid that includes an implanted actuator), which comprise a test measurement device (programming system 22 in combination with implanted hearing aid 12) having a signal generator (DSP 13) to output a test signal at a predetermined frequency, wherein the hearing aid passes at least one electrical signal through the hearing aid actuator (16) in response to the test signal; voltage and current measurement logic (impedance measuring system 25 – see column 14, lines 33-36) to measure a voltage and a current of the at least one electrical signal (column 14, line 60 –column 15, line 19); and a signal processing unit (13) to process the voltage and current measurements to compute at least one impedance measure and to provide an output usable to assess the performance of the hearing aid (column 16, lines 36-40).

The inherent normal method of testing the quality of the coupling of the actuator a component of a patient's auditory system according to the system of Leysieffer would comprise positioning a test measurement device (element 22 of Fig. 1) external to a patient having an implanted hearing aid that includes a hearing aid actuator; utilizing the test measurement device to generate at least one predetermined test signal that is provided by the test measurement device to the hearing aid and to obtain at least one impedance measure of the hearing aid actuator, responsive to a resultant electrical signal passing through the hearing aid actuator (column 14, lines 44-48 and claim 13); and employing the at least one impedance measure to assess the performance of the hearing aid actuator (claim 1). Leysieffer does not disclose that the test measurement device that generates the test signal at a predetermined frequency is (completely) separate from and positioned external to a patient having the implanted hearing aid. Hochmair et al. discloses in Fig. 1, a method of fitting a hearing aid (such as cochlear implant or a conventional hearing aid), in which a test measurement device that is separate from and positionable external to a patient having an implanted hearing aid generates a plurality of predetermined test signals that are transmitted to an implanted transducer (see column 3, line 14 –column 5, line 15). This method of applying test signals to a hearing aid from an external test device (either through a transcutaneous transmitter/receiver arrangement or through a loudspeaker projecting acoustic waves to a microphone of the hearing aid, as described at column 3, lines 41-43) has long been well known in the art. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to generate the audio test signal in the

programming system (22) of Leysieffer, external to the hearing aid and the patient, as taught by Hochmair et al., in order to simplify the programming of the DSP (13) of the implanted hearing aid of Leysieffer, and/or in order to avoid the prior art.

4. Regarding claims 2, 3, 22, and 23, Leysieffer discloses at column 6, lines 46-63 that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance. Objective determination based on measured quantities inherently comprises comparing the measured quantities to a one or more predetermined ranges. Leysieffer discloses at column 13, line 66 through column 14, line 7 that the microcontroller (17) of the implanted hearing aid communicates bi-directionally through the closed skin with an external programming system (22), which can advantageously be a PC-based system with the corresponding programming, processing, display, and administration software. Although Leysieffer does not explicitly disclose the detailed nature of the output provided to the operator of the system, one of ordinary skill in the art would conclude that means are included within the programming system (a signal processor) to provide a user-interface output, via a display of the PC-based programming system, indicative of whether the measured quantities are within predetermined ranges. Since the disclosed inventive feature of the test apparatus of Leysieffer is measuring the quality of coupling between an actuator of an implanted hearing aid and the coupled auditory component of the patient's ear, and Leysieffer discloses at column 6, line 54 –column 7, line 7 that the coupling quality can be judged

and, if necessary, improved through use of the system, the method inherently comprises comparing the impedance measure to a first predetermined range to assess an interface between the hearing aid actuator and a component of an auditory system of the patient.

5. Regarding claim 8, Leysieffer discloses in Fig. 11, an alternate embodiment in which a passive electronic module (77) and actuator (16) are implanted within a patient and an external unit (76) comprises a microphone (10), signal processing module (74), battery (3), and modulator/transmitter (75). Leysieffer discloses at column 21, lines 9-13 that the implanted electronic module (77) and the modulator/transmitter unit (75) include the necessary telemetry unit for transmission of the impedance measuring data to the external module (76) for further evaluation, but does not disclose specifically how the impedance measurement data is further evaluated or utilized. According to the general teachings of Leysieffer, as in the embodiment of Figs. 1, 6, and 7, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to selectively interconnect programming system (22) (the test measurement device) to the external transmitter (76 of Fig. 11) of the hearing aid, transmitting the at least one predetermined test signal from the test measurement device (programming system 22) to the external transmitter (76), according to the teachings of Hochmair et al. as described above regarding claim 1; and inductively coupling the at least one test signal between the external transmitter and a subcutaneous coil of the hearing aid.

6. Regarding claim 9, Hochmair et al. discloses at column 3, lines 41-43 that if a hearing aid (as opposed to a cochlear implant) has to be checked, the test signal is applied to the patient wearing the aid via a loudspeaker. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to apply this further teaching to the implanted hearing aid system of Leysieffer by transmitting the at least one predetermined test signal to a speaker located external to the patient, wherein the at least one predetermined test signal is acoustically provided by the speaker to an implanted microphone of the hearing aid in order to conveniently couple a test signal into the hearing aid using the existing microphone.

7. Regarding claim 17, Leysieffer discloses at column 7, lines 41-44 that an impedance measure is computed from the voltage and current measurements. While Leysieffer does not disclose that the measured voltage and current are obtained in the (external) test measurement device, the option of transmitting the actuator voltage and current measures to an external test device for subsequent calculation of an impedance therein, as opposed to calculating the actuator impedance within the implanted hearing aid and transmitting the resulting calculated impedance measure to the external test device is an obvious design choice, which does not produce any new or unexpected result. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to calculate the actuator impedance either within the hearing aid or within the external test device as convenient.

8. Regarding claims 18, 19, 27, and 28, Leysieffer discloses at column 8, lines 1-17 that impedance measurements (and thus voltage and current measurements) are made at frequencies extending over the entire transmission frequency range of the output transducer (actuator), which inherently requires providing a plurality of predetermined test signals having different frequencies distributed across a predetermined frequency range for use in generating a corresponding plurality of electrical signals passing through the actuator and using the test measurement device to obtain a plurality of impedance measures corresponding to the plurality of electrical signals passing through the actuator.

9. Regarding claim 20, Leysieffer discloses at column 8, lines 23-31, means for detecting (and thus identifying) the spectral distribution of resonance frequencies of the transducer in the course of the impedance measured as a function of the frequency of the stimulation signal.

10. Regarding claim 26, as broadly as claimed, any test signal has a frequency that is within some (predetermined) range of a resonant frequency of an actuator. Additionally, Leysieffer discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies, which inherently requires providing test signals at those resonant frequencies.

11. Regarding claim 31, the signal generators taught by both Leysieffer and Hochmair et al. comprise an oscillator (a device for producing an alternating current, inherently); a test control processor to set the oscillator to generate the test signal (microcontroller 17 of Leysieffer, computer 10 of Hochmair et al.); and a reference transmitter to provide the test signal to one of a speaker (column 3, lines 32-43 of Hochmair et al.) and an external transmitter of the hearing aid (inherently part of programming system 22 of Fig. 1 of Leysieffer; also, see column 2, lines 49-53 of Hochmair et al.).

12. Regarding claim 35, in the test measurement device of Leysieffer, modified according to the teachings of Hochmair et al. as described above regarding claim 21 to generate the audio test signals in the programming system (22) of Leysieffer, external to the hearing aid and the patient, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to include a signal processing unit in the external test device since, in the original system of Leysieffer, the test signals were generated in such a signal processor (13) in the implanted hearing aid.

13. Claims 4, 5, 7, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer (US 6,554,762) in view of Hochmair et al. (US 4,577,641) as applied to claims 1-3 and 21-23 above, and further in view of Hayashi et al. (JP 60216695 A) and Urano (JP 07239993 A).

14. Regarding claims 4, 5, 24, and 25, Leysieffer discloses at column 6, lines 46-63 that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance. Objective determination based on measured quantities inherently comprises comparing the measured quantities to a one or more predetermined ranges. Leysieffer does not explicitly disclose comparing the at least one impedance measure to a second predetermined range to assess the operability of the hearing aid, wherein the second predetermined range is at least partially non-overlapping with a first predetermined range used to assess an interface between the hearing aid actuator and a component of an auditory system of the patient. Hayashi et al. discloses a device and associated method for testing an acoustic actuator (a loudspeaker) by measuring the impedance of the actuator in response to AC test signals passing through the actuator and comparing a resultant impedance measure to a predetermined value or range of values to provide an output indicating the condition of the actuator (see English abstract). Urano discloses a similar testing device for measuring the impedance of an acoustic actuator (a loudspeaker) in response to an AC signal, comparing the measured impedance to a predetermined range to determine if the actuator is operable (not open circuited or short circuited), and providing an output indicative of whether the impedance measure is within the predetermined range (see English abstract). It would have been obvious to one of ordinary skill in the art at the time the present invention was made to apply the teachings of Hayashi et al. and Urano to the system and method of Leysieffer, modified according to the teachings of Hochmair et al. by comparing the measured

impedance value obtained with a second predetermined range (which would inherently be at least partially non-overlapping with a range used to determine a proper interface between the actuator and an auditory component of a patient), utilizing appropriate means such as the signal processing unit, and providing an output through the user interface, indicative of whether the actuator is within a second predetermined range, in order to easily determine if the implanted actuator is functional.

15. Regarding claim 7, as broadly as claimed, any test signal has a frequency that is within some (predetermined) range of a resonant frequency of an actuator. Additionally, Leysieffer discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies, which inherently requires providing test signals at those resonant frequencies.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 32-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 19 and 21 of copending Application No. 10/083,181.

18. The combination of claims 14, 19, and 21 in the copending application forms a method for assessing the performance of a hearing aid that includes an implanted hearing aid actuator comprising: positioning a test measurement device external to a patient having an implanted hearing aid that includes a hearing aid actuator (claim 14); utilizing the test measurement device to obtain at least one impedance measure of the hearing aid actuator responsive to an electrical signal passing through the hearing aid actuator (claims 19 and 21, as supported by paragraph [0072] of the published Application No. 10/083,181, Pub. No. US 2003/0163022); employing the at least one

impedance measure to assess an interface between the actuator and a component of an auditory system of the patient (claim 16); providing an electrical input to a positioning system responsive to said assessment of said interface, to selectively position the hearing aid actuator relative to the component of the auditory system (claim 11), wherein the step of providing the electrical input comprises providing a wireless signal to the positioning system from a position external to the patient (claim 12); and wherein the step of providing the electrical input comprises inductively coupling the electrical input to the positioning system (claim 13). It would have been obvious to one of ordinary skill in the art to combine these various features and steps of the co-pending application in order to form a completely operative device and method.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

19. Applicant's arguments with respect to claims 1 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

21. Bartz (US 3,752,939) discloses an implanted hearing aid (a cochlear electrode implant system), which receives signals transcutaneously from an external unit comprising a microphone, oscillator/transmitter, and transmitting antenna in use. The disclosure implies an external test apparatus generates signals and transmits them to the hearing aid during the implantation process (see column 9, lines 21-41).

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony M Jacobson whose telephone number is 703-305-5532. The examiner can normally be reached on M-F 11:00-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Forester W Isen can be reached on 703-305-4386. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINSUN OH HARVEY
PRIMARY EXAMINER

tmj
March 4, 2004